Testimony of Dr. James Phillips

Madam Chairwoman and members of the committee thank you for providing me the opportunity to testify in front of you today on an issue that I find extremely important and one that is extremely important for the state. House Bill 5934 provides the tool that physicians can use to curb the spread of two sexual transmitted infections – the tool is expedited partner therapy or EPT.

This bill allows the physician to treat the patient's partners who have either Gonorrhea or Chlamydia by writing a prescription for the partner who is not present for the visit. Provision of the specific antibiotics in this way has been proven to be both safe and effective. This tool will help physicians combat the current spread of these sexually transmittable infections by more efficiently reaching and treating partners. If not promptly treated, the partner will likely re-infect the patient and may possibly move to different partners and infect more people. The spread of the infection can be seen as an onion. You start in the center of the onion and those who are infected move out of the center into other layers as they infect more people. With EPT physicians can head this off by treating more quickly and reliably all sexual partners. Unfortunately in Michigan EPT is not currently an option. Many partners don't get medical attention because the infected patient may be reluctant to identify him or her by name, or if identified, public health officials have difficulty finding and treating them. In addition many partners may not feel that easy and affordable treatment is available for them. They may delay seeking care especially if they are having minimal symptoms, need transportation to the clinic or must take time off from work to be seen. EPT would be very helpful in these cases.

Michigan physicians have been fighting these infections for years and have seen sharp rises in the past ten years. The fastest growing sectors of the population with cases of these two infections are young adults and surprisingly also the elderly. With elders moving into retirement communities and assisted living, we are finding that sexually transmitted disease is on the rise there. EPT provides a simple solution to help stunt the rise of cases in these populations. In the young adult population these two STDs can produce devastating pregnancy complications including death from a tubal pregnancy. The fallopian tubes can be scarred as a result of Gonorrheal or Chlamydia pelvic inflammatory disease. The tubes may be completely blocked resulting in infertility, or partially blocked leading to a tubal pregnancy. The newborn infant of an infected mother often is exposed during delivery and may become seriously ill. EPT can be an effective tool to help preserve fertility and successful pregnancy outcomes for women and their babies. EPT facilitates early treatment of female partners and reduces their chances of developing devastating pelvic infections.

EPT has been shown nationally to decrease the amount of Gonorrhea or Chlamydia cases in the states where it has been put into place. 43 states including the District of Columbia and Puerto Rico all have EPT and all have seen sharp declines in the infection and have all seen savings associated with that decline. The Centers for Disease Control after studying the effects of EPT concluded, "EPT represents an additional strategy for partner management that does not replace other strategies such as provider-assisted referral, when available."

House Bill 5934 offers a crucial tool to Michigan physicians working hard to protect Michigan's Public Health. As you will hear later, in addition to my state medical society, EPT has gained support of the Michigan section of the American Congress of Obstetricians and Gynecologists, American Medical Association, the Centers for disease Control, the Snyder Administration, and others. Today we ask that you please support and pass House Bill 5934 to give that effective tool to Michigan's physicians. Thank you for your time and consideration. I would be happy to answer any question you have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

May 11, 2005

Dear Colleague,

Effective clinical management of patients with treatable sexually transmitted diseases (STDs) requires treatment of the patients' current sex partners to prevent reinfection and curtail further transmission. The standard approach to partner treatment has included clinical evaluation in a health care setting, with partner notification accomplished by the index patient, by the provider or an agent of the provider, or a combination of these methods. Provider-assisted referral is considered the optimal strategy for partner treatment, but is not available to most patients with gonorrhea or chlamydial infection because of resource limitations.[1] The usual alternative is to advise patients to refer their partners for treatment.

In recent years, research supported by CDC has evaluated expedited partner therapy (EPT), an approach whereby partners are treated without an intervening clinical assessment. EPT typically is accomplished by patients delivering either medications or prescriptions to their partners.[2-5] Although used by many clinicians in the U.S.,[6] EPT has not been generally recommended as a partner management strategy. With the assistance of representatives from the public and private health care sectors assembled in two advisory consultations, CDC recently reviewed the available evidence concerning EPT for gonorrhea and chlamydial infection, including three published or in-press randomized controlled trials.[2-4] The review considered the effect of EPT on reinfection rates among patients and on patient and sex partner behaviors expected to reduce reinfection. The review also examined the existing barriers to EPT implementation.

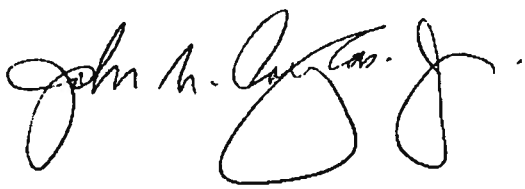
CDC has concluded that EPT is a useful option to facilitate partner management, particularly for treatment of male partners of women with chlamydial infection or gonorrhea. Although ongoing evaluation will be needed to define when and how EPT can be best utilized, the evidence indicates that EPT should be available to clinicians as an option for partner treatment. EPT represents an additional strategy for partner management that does not replace other strategies such as provider-assisted referral, when available. Along with medication, recipients of EPT should also receive information about the desirability of clinical evaluation in addition to EPT. This is particularly important when EPT is provided for female recipients and for men with symptoms. There is no experience with EPT for gonorrhea or chlamydial infection among men who have sex with men.

In the coming months, CDC will release documents that review the evidence concerning EPT efficacy, describe promising practices and limitations, and provide recommendations for implementation. In addition, CDC guidance regarding the practice

and application of EPT strategies will be incorporated into the coming revision of the STD Treatment Guidelines.

At present, recommendations to employ EPT are not feasible in many settings because of several operational barriers, including the uncertain legal status of EPT in some states.[7] Therefore, CDC strongly encourages individuals, local and state health departments, and other organizations interested in STD prevention to work together to resolve such barriers. To maximize the STD prevention impact of EPT, public health programs, managed care organizations, professional associations, private health care providers, and other clinicians should seek opportunities to work with policy makers and other stakeholders to identify and address legal and administrative barriers to its use.

Sincerely,



John M. Douglas, Jr., MD
Director, Division of STD Prevention
National Center for HIV, STD and TB Prevention

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2. Schillinger JA, Kissinger P, Calvet H, et al. Patient-delivered partner treatment with azithromycin to prevent repeated *Chlamydia trachomatis* infection among women: a randomized controlled trial. *Sex Transm Dis* 2003;30:49-56.
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EXECUTIVE SUMMARY

Overview

Expedited partner therapy (EPT) is the practice of treating the sex partners of persons with sexually transmitted diseases (STD) without an intervening medical evaluation or professional prevention counseling. The usual implementation of EPT is through patient-delivered partner therapy (PDPT), although other methods may be employed. The available literature and selected unpublished studies were systematically reviewed, and this report provides background for the development of guidance on use of EPT as an option for partner management for selected STDs and patients.

Evidence

For STDs other than syphilis, partner management based on patient referral or provider referral has had only modest success in assuring partner treatment, largely attributable to limitations of available financial and personnel resources. EPT is believed to have been widely employed in women with trichomoniasis. Recent surveys document occasional use by many primary care providers in the management of patients with gonorrhea and chlamydial infection, and consistent use by a few. A retrospective case control study and two process-oriented analyses suggested that EPT holds promise as a partner management option. These studies contributed to CDC decisions to fund 4 randomized controlled trials (RCTs) designed to compare EPT with standard partner management approaches in men and women with gonorrhea, chlamydial infection, or trichomoniasis; and to assess behavioral predictors of treatment and reinfection.

Persistent or Recurrent Infection

The first RCT of EPT followed 1,787 women in 6 cities after treatment for chlamydial infection. Recurrent infection was documented at follow-up visits 1 months and 4 months later in 12% of women randomized to EPT and 15% of those managed by patient referral (odds ratio [OR] 0.80, 95% confidence interval [CI] 0.62-1.05). The second RCT enrolled 2,751 men and women with gonorrhea or chlamydial infection from both public and private care settings in a single metropolitan area. Persistent or recurrent infection with either disease was found in 9.9% of subjects randomized to EPT and 13.0% of those who had standard patient-referral or provider-referral of their partners (OR 0.76, 95% CI 0.59-0.98). EPT was more effective in preventing gonorrhea at follow-up (OR 0.32, 95% CI 0.13-0.77) than chlamydial infection (OR 0.82, 95% CI 0.62-1.07). Chlamydial infection was present at follow-up in 7.6% of women who denied all sex since treatment, suggesting that a higher than expected rate of treatment failure accounted for some infections at follow-up. In the third available RCT, 977 men with symptomatic urethritis (principally gonorrhea and chlamydial infection) were randomized to EPT, patient referral, or patient referral enhanced by written education materials. Follow-up testing for gonorrhea and chlamydial infection 4-8 weeks later was accomplished in 37.5% of patients. Persistent or recurrent infection was found in 43% of subjects in the patient referral group (referent), 14% of men randomized to enhanced patient referral (OR 0.22, 95% CI 0.11-0.44, P<0.001), and 23% of men randomized to EPT (OR 0.38, 95% CI 0.19-0.74, P<0.001). For trichomoniasis, in an as yet unpublished RCT of 463 women randomized to the same interventions as the male

urethritis trial, with 80% follow-up, the prevalences of infection 3-7 weeks later were not significantly different for patient referral (6%), enhanced patient referral (9%), or EPT (9%).

Behavioral Outcomes

The 4 available RCTs evaluated the association of EPT with index cases' reports of success in partner notification, confidence that their partners were treated, and sexual behaviors likely to predict reinfection. In 2 trials that enrolled male index cases, men randomized to EPT were equally or more likely to notify their partners than those randomized to the control strategies. Female index cases with chlamydial infection or gonorrhea who were randomized to EPT had either equivalent success or enhanced success in notifying partners compared with women randomized to standard partner management. In all 3 trials of gonorrhea or chlamydial infection, EPT was associated with at least equivalent and typically increased confidence by both male and female index cases that their partners had received treatment, including direct observation that their partners took medication. Two trials that addressed both gonorrhea and chlamydial infection found EPT to be associated with significantly reduced rates of sex with untreated partners at follow-up. The trichomoniasis trial showed general equivalence of EPT with desirable behavioral outcomes compared with standard patient referral.

Cost Effectiveness

Preliminary economic analyses suggest that EPT is a cost-saving and cost effective partner management strategy.

Limitations

The data available to support EPT for chlamydial infection were derived in larger and geographically more diverse samples of patients than those for gonorrhea. Nevertheless, the evidence in favor of EPT, as measured by the rate of persistent or recurrent infection at follow-up, is stronger for gonorrhea than for chlamydial infection, perhaps due to a higher than expected rate of persistent chlamydial infection in women. This finding confounds the assessment of EPT in women with chlamydial infection. Assuring the treatment of infected men's female partners is a high priority to prevent ongoing transmission and community spread.

As for all RCTs, the extent to which the results of the available trials can be safely generalized to other populations and settings is not certain. Owing to modest sample sizes in some disease-specific patient groups, and varying effect sizes, not all outcomes of interest have been shown to be statistically significant. For example, further data are desirable on the use of EPT in male index cases. The available data do not support the routine use of EPT in the management of trichomoniasis, and no published data support the use of EPT for chlamydial infection or gonorrhea in men who have sex with men (MSM). Although substantial numbers of adolescents were included in the available trials, there is little experience in patients <18 years old.

Issues in Implementation of EPT

Among several pragmatic issues that will influence implementation of EPT as an STD prevention strategy, a dominant one is the possibility of undetected STD in partners. The potential for undiagnosed pelvic inflammatory disease (PID) is of concern when EPT is used to treat the female partners of men with gonorrhea or chlamydial infection. Therefore, EPT intended for female partners should be accompanied by warnings about the symptoms of PID and advice that women seek medical attention in addition to accepting treatment. Undiagnosed gonorrhea and chlamydial infection are common in the partners of women with trichomoniasis, and undiagnosed HIV infection and other morbidities have been found in many partners of STD-infected MSM.

The legality of EPT is uncertain in some states and overt statutory impediments exist in others; the practice is clearly legal only in a few states. The medicolegal ramifications may be uncertain in the event of adverse outcomes in the recipients of EPT. Other barriers include direct and indirect costs, including limitations on third-party insurance coverage; missed opportunities for prevention counseling of partners; risks of allergic reactions and other adverse drug effects; administrative barriers; privacy issues; and the attitudes and beliefs of health care providers and agencies about the practice.

Conclusions

Both clinical and behavioral outcomes of the available studies indicate that EPT is a useful option to facilitate partner management among heterosexual men and women with chlamydial infection or gonorrhea. The evidence indicates that EPT should be available to clinicians as an option for partner management, although ongoing evaluation will be needed to define when and how EPT can be best utilized. EPT represents an additional strategy for partner management that does not replace other strategies, such as standard patient referral or provider-assisted referral, when available. Along with medication, EPT should be accompanied by information that advises recipients to seek personal health care in addition to EPT. This is particularly important when EPT is provided to male patients for their female partners, and for male partners with symptoms. Existing data suggest that EPT has a limited role in partner management for trichomoniasis. No data support its use in the routine management of syphilis, and there is no experience with EPT for gonorrhea or chlamydial infection among MSM.

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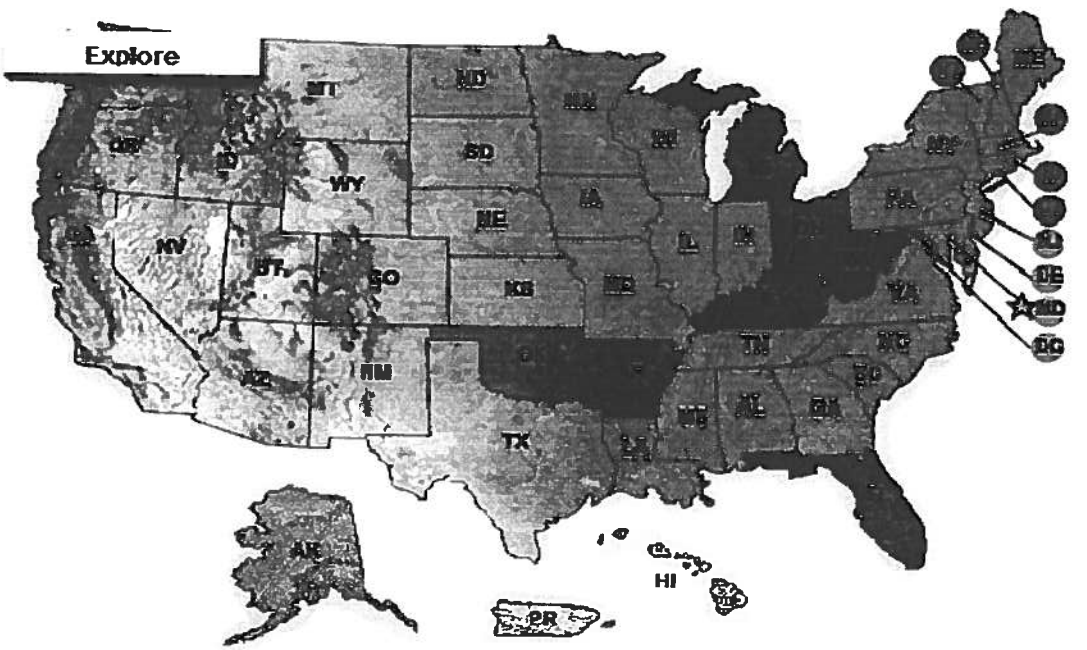
Sexually Transmitted Diseases (STDs)

Legal Status of Expedited Partner Therapy (EPT)

The information presented here is not legal advice, nor is it a comprehensive analysis of all the legal provisions that could implicate the legality of EPT in a given jurisdiction.

To view information for each state, click on state in the map below. Summary Totals are here (totals.htm) .



EPT is permissible in 32 states:	EPT is potentially allowable in 11 states:	EPT is prohibited in 7 states:
Alaska (alaska.htm)	Alabama (alabama.htm)	Arkansas (arkansas.htm)
Arizona (arizona.htm)	Delaware (delaware.htm)	Florida (florida.htm)
California (california.htm)	Georgia (georgia.htm)	Kentucky (kentucky.htm)
Colorado (colorado.htm)	Hawaii (hawaii.htm)	Michigan (michigan.htm)
Connecticut (connecticut.htm)	Kansas (kansas.htm)	Ohio (ohio.htm)
Idaho (idaho.htm)	Maryland (maryland.htm)	Oklahoma (oklahoma.htm)
Illinois (illinois.htm)	Montana (montana.htm)	West Virginia (westvirginia.htm)
Indiana (indiana.htm)	Nebraska (nebraska.htm)	
Iowa (iowa.htm)	New Jersey (newjersey.htm)	
Louisiana (louisiana.htm)	South Dakota (southdakota.htm)	
Maine (maine.htm)	Virginia (virginia.htm)	
Massachusetts (massachusetts.htm)		

Minnesota (minnesota.htm) Mississippi (mississippi.htm) Missouri (missouri.htm) Nevada (nevada.htm) New Hampshire (newhampshire.htm) New Mexico (newmexico.htm) New York (newyork.htm) North Carolina (northcarolina.htm) North Dakota (northdakota.htm) Oregon (oregon.htm) Pennsylvania (pennsylvania.htm) Rhode Island (rhodeisland.htm) South Carolina (southcarolina.htm) Tennessee (tennessee.htm) Texas (texas.htm) Utah (utah.htm) Vermont (vermont.htm) Washington (washington.htm) Wisconsin (wisconsin.htm) Wyoming (wyoming.htm) ★ **Exception:** EPT is permissible in Baltimore, Maryland (maryland.htm).	EPT is potentially allowable in District of Columbia (dc.htm) and Puerto Rico (puertorico.htm).	

Summary Totals (totals.htm)

Introduction

Assuring treatment of the sex partners of persons with sexually transmitted diseases (STD) has been a central component of prevention and control of bacterial STDs in the United States for decades. Traditional practices to inform, evaluate and treat sex partners of persons infected with STDs have relied upon patients or health care providers to notify partners of infected persons of their exposure to an STD. Initially developed to help control syphilis, partner management became widely recommended for gonorrhea, chlamydial infection and, most recently, human immunodeficiency virus (HIV) infection. However, for STDs other than syphilis, partner management based on provider referral is rarely assured, while patient referral has had only modest success in assuring partner treatment.

An alternative approach to assuring treatment of partners is expedited partner therapy (EPT). EPT is the delivery of medications or prescriptions by persons infected with an STD to their sex partners without clinical assessment of the partners. Clinicians (e.g., physicians, nurse practitioners, physician assistants, pharmacists, public health workers) provide patients with sufficient medications directly or via prescription for the patients and their partners. After evaluating multiple studies involving EPT, CDC concluded that EPT is a "useful option" to further partner treatment, particularly for male partners of women with chlamydia or gonorrhea (../../treatment/EPTFinalReport2006.pdf#page=35). In August 2006, CDC recommended the practice of EPT for certain populations and specific conditions in its Sexually Transmitted Diseases Treatment Guidelines, 2006 (../../treatment/default.htm).

Throughout discussions of EPT, the legal status of the practice remained an area of uncertainty. To assist state and local STD programs in their efforts to implement EPT as an additional partner services tool, CDC collaborated with the Center for Law and the Public's Health (http://www.publichealthlaw.net) (http://www.cdc.gov/Other/disclaimer.html) at Georgetown and Johns Hopkins Universities to assess the legal framework concerning EPT

across all 50 states and other jurisdictions (the District of Columbia and Puerto Rico). The primary research objective was to conceptualize, frame, and identify legal provisions that implicate a clinician's ability to provide a prescription for a patient's sex partner, without prior evaluation of that partner, for purposes of treating an STD (specifically chlamydia or gonorrhea). The results of this research, with explanatory information for six key areas of inquiry (#a3.htm) and summary conclusions for each state are presented here.

The information presented here is not legal advice, nor is it a comprehensive analysis of all the legal provisions that could implicate the legality of EPT in a given jurisdiction. Rather, it provides a comparative snapshot of legal provisions that may highlight legislative, regulatory, judicial laws and policies concerning EPT based on currently available information. This snapshot is subject to change. Measuring the legal weight of non-binding legal sources, such as policy guidance documents or administrative decisions, must be done locally within the context of applicable statutes and regulations. The data and assessment are intended to be used as a tool to assist state and local health departments as they determine locally appropriate ways to control STDs. Assessment of local statutes was not undertaken, with the exception of the District of Columbia. Assessment of tribal laws for sovereign nations was also not undertaken.

Explanation

Sections I - VII categorize key legal provisions implicating EPT as follows:

I. **Existing statutes/regulations that specifically address the ability of authorized health care providers to provide a prescription for a patient's partner(s) without prior evaluation for certain STDs.** Section I includes statutory or regulatory provisions that specifically address whether a health care provider may provide a prescription for a patient's partner without a prior evaluation or relationship with the partner. While these provisions may be limited in their application, they may effectually either authorize or prohibit EPT in specific circumstances. For example, a few states feature statutes or regulations that directly authorize some health care professionals to conduct EPT. These laws typically specify the STDs for which EPT is authorized as well as the health care professionals who are authorized to conduct EPT.

II. **Specific judicial decisions concerning EPT (or like practices).** Section II includes judicial decisions (case law) that implicate the legality of EPT or "like practices" (practices that are legally similar to EPT). Case law decisions are legally binding in their jurisdictions and set legal precedent for future decisions.

III. **Specific administrative opinions by the Attorney General or medical or pharmacy boards concerning EPT (or like practices).** Section III includes publicly-available decisions by state administrative bodies that discuss the legality of EPT or like practices. These decisions can include opinions of the state Attorney General, actions by medical disciplinary boards, advisory decisions or resolutions of medical or pharmacy boards, or general policy guidelines. Attorney General opinions are only binding on the party who sought the opinion, but the opinion may indicate how EPT may be regarded in the future.

IV. **Legislative bills or prospective regulations concerning EPT (or like practices).** Section IV includes recent legislative or regulatory actions that would authorize or prohibit EPT or like practices. Although these bills or regulations have not been passed into law, they provide a glimpse as to potential future legality of EPT.

V. **Laws that incorporate via reference guidelines as acceptable practices (including EPT).** Section V includes legal provisions that allow public health or clinical

practices to be incorporated by reference through specific guidelines. Even if the current legal status of EPT in a jurisdiction is unclear, EPT could become legally permissible if a designated published guideline, agency, or official adopted EPT as an acceptable treatment method. The contents of these guidelines are incorporated by reference, which means they have the force of law in that jurisdiction. Legalization of EPT may thus be furthered by consulting with the organization that publishes the guideline or the agency official to recognize EPT as an acceptable treatment method for specific STDs provided such recommendation does not conflict with other legal provisions. The following abbreviations are used in this column of the table:

- "CDC STD Treatment Guidelines" refers to *Sexually Transmitted Diseases Treatment Guidelines (../../treatment/default.htm)* published by CDC through its Morbidity and Mortality Weekly Reports (which explicitly supports the use of EPT for certain STDs and populations);
- "APHA's CCD Manual" refers to the *Control of Communicable Diseases in Man* published by the American Public Health Association; and
- "AAP's Red Book" refers to the *Red Book: Report of the Committee on Infectious Diseases* published by the American Academy of Pediatrics.

VI. **Prescription requirements.** Section VI includes statutory or regulatory provisions that relate to prescription drug laws (other than for controlled substances) in each jurisdiction to the extent they may impact EPT. This may include:

1. laws that require prescription orders or labels to indicate identifying information about the person for whom the prescription is intended. If identifying information is not required, it may facilitate a physician writing a prescription for a patient to deliver to her partner without identifying the partner. While these laws do not necessarily implicate the legality of EPT, they affect how EPT may be implemented in practice. If patient-identifying information is required, a physician may not be legally permitted to provide a blank prescription or an "extra dose" for the patient to deliver to the partner. Instead, such a prescription may have to be made out in the partner's name;
2. laws that concern the pharmacists' need to verify a physician-patient relationship or that an individual has been examined by a physician prior to dispensing pharmaceutical products; or
3. laws that require a pharmacist to ensure that drugs are dispensed to an ultimate user of the prescription.

VII. **Assessment of the legal status of EPT.** Section VII provides an assessment whether the various laws of the jurisdiction tend to support or reject the legality of EPT. One of three conclusions is indicated for each jurisdiction:

☑ - **EPT is permissible** for certain practitioners and conditions;

~ - **EPT is potentially allowable** subject to additional actions or policies (this may include specific interpretations of inconsistent or amorphous provisions, supporting policies consistent with legal authorization, or incorporation by reference into treatment guidelines); or

☒ - **EPT is likely prohibited.**

Each of these initial conclusions is followed by brief comments providing some justification for the assessment.

Limitations

The information presented here is not legal advice, nor is it a comprehensive analysis of all the legal provisions that could implicate the legality of EPT in a given jurisdiction. Rather, it provides a comparative snapshot of legal provisions that may highlight legislative, regulatory,

judicial laws and policies concerning EPT based on currently available information. This snapshot is subject to change. Measuring the legal weight of non-binding legal sources, such as policy guidance documents or administrative decisions, must be done locally within the context of applicable statutes and regulations. The data and assessment are intended to be used as a tool to assist state and local health departments as they determine locally appropriate ways to control STDs. Assessment of local statutes was not undertaken, with the exception of the District of Columbia. Assessment of tribal laws for sovereign nations was also not undertaken.

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Sexually Transmitted Diseases (STDs)

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Legal Status of EPT - Summary Totals

I. Statutes/regs on health care providers' authority to prescribe for STDs to a patient's partner(s) w/out prior evaluation (Explanation)	✚ 28 states feature one or more laws that permit or may facilitate certain health care practitioners to practice EPT. ✚ Maryland permits EPT in Baltimore on a pilot basis. ● 24 states feature one or more laws that may limit the ability of some health care practitioners to conduct EPT.
II. Specific judicial decisions concerning EPT (or like practices) (Explanation)	● 6 states feature one or more judicial decisions that disallow prescriptions to persons without a physical examination or physician-patient relationship.
III. Specific administrative opinions by the Attorney General or medical or pharmacy boards concerning EPT (or like practices) (Explanation)	✚ 13 states feature an agency opinion that supports EPT or like practices. ● 13 states feature agency opinions that tend to prohibit EPT or like practices.
IV. Legislative bills or prospective regulations concerning EPT (or like practices) (Explanation)	✚ 1 state features proposed legislative bills to authorize EPT (2011 legislative session): Virginia. ✚ 4 states have attempted to pass legislation, in previous sessions, to authorize EPT: Montana, Nebraska, Nevada, and Oklahoma
V. Laws that incorporate via reference guidelines as acceptable practices (including EPT) (Explanation)	✚ 9 states have incorporated via reference CDC's STD Treatment Guidelines. ✚ 13 states have incorporated via reference APHA's CCD Manual. ✚ 5 states have incorporated via reference the AAP Red Book. ✚ 6 states have incorporated via reference other guidelines or recommenda-tions.
VI. Prescription requirements (Explanation)	● 36 states feature laws that require some patient identifying information on the prescription order or label.

➕ 10 states' laws do not require patient identifying information on prescription order or label.

⚫ 13 states have statutory provisions prohibiting pharmacists from dispensing medications to individuals who have not undergone a physical examination, failed to establish a physician-patient relationship, or who are not the ultimate user (i.e., a third-party) pursuant to a valid prescription.

VII. Assessment of EPT's legal status with brief comments (Explanation)

☑ EPT is permissible in 32 states and Baltimore, Maryland.

〜 EPT is potentially allowable in 11 states, the District of Columbia, and Puerto Rico.

☒ EPT is likely prohibited in 7 states.

Status as of July 1, 2012

Legend

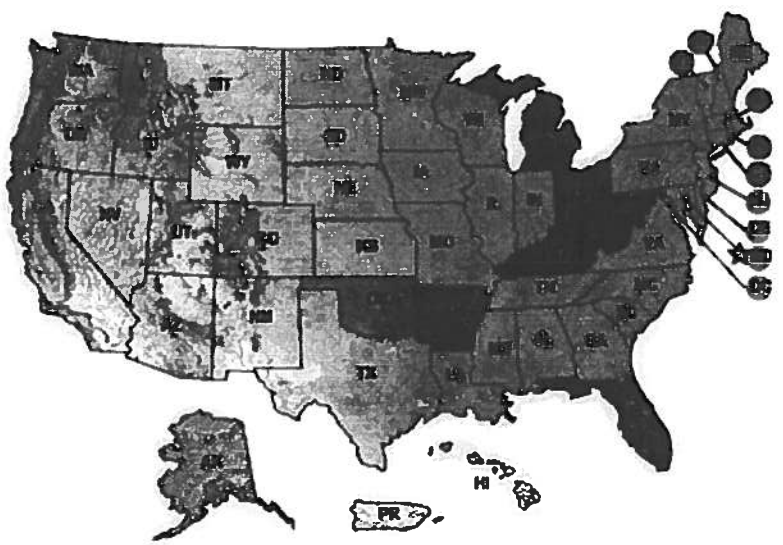
➕ supports the use of EPT

⚫ negatively affects the use of EPT

☑ EPT is permissible

〜 EPT is potentially allowable

☒ EPT is prohibited



★ Exception: EPT is permissible in Baltimore, Maryland.

Alabama
Alaska

Summary Totals

Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin

Wyoming
Summary Totals

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Sexually Transmitted Diseases (STDs)

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Legal Status of EPT in Michigan

☒ **EPT is likely prohibited.**

I. Statutes/regs on health care providers' authority to prescribe for STDs to a patient's partner(s) w/out prior evaluation (Explanation)

● Prescribing practitioner can only dispense prescription drugs to the practitioner's own patients. Mich. Comp. Laws Ann. § 333.17745. Note, the above provision does not apply to providing a prescription order to a patient.

II. Specific judicial decisions concerning EPT (or like practices) (Explanation)

III. Specific administrative opinions by the Attorney General or medical or pharmacy boards concerning EPT (or like practices) (Explanation)

IV. Legislative bills or prospective regulations concerning EPT (or like practices) (Explanation)

V. Laws that incorporate via reference guidelines as acceptable practices (including EPT) (Explanation)

VI. Prescription requirements (Explanation)

● Prescription cannot be dispensed unless patient's name and record number are on the prescription label. Mich. Comp. Laws Ann. § 333.177457; see also Pharmacy Board rule R 338.479.

● Pharmacist must provide purchaser of prescription drug a receipt which includes patient name. § 333.17757

● Pharmacist may not dispense prescription drugs unless s/he determines that the prescription is pursuant to an existing physician/patient relationship. Mich. Comp. Laws Ann. § 333.17751.

● A prescriber who issues a written prescription for a noncontrolled legend drug . . . shall ensure that the prescription contains...(a) The full name of the patient for whom the drug is being prescribed...." Mich. Admin. Code r 338.479(b)

VII. Assessment of EPT's legal status with brief comments (Explanation)

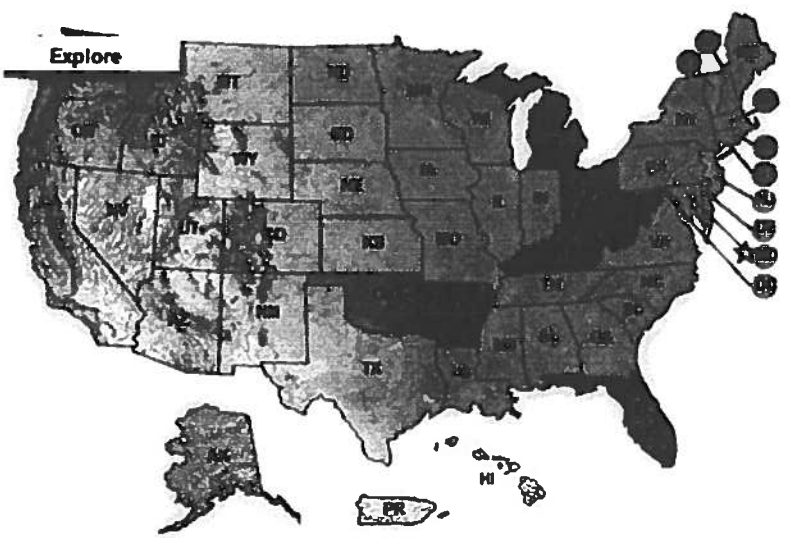
☒ EPT is likely prohibited.

Statutory law requires that drugs be dispensed to a physician's own patients, narrowing the class of legitimate recipients to individuals who have expressly established a physician patient relationship. Pharmacists must ensure that all prescriptions are dispensed pursuant to a valid physician patient relationship.

Status as of August 16, 2006

Legend

- ✚ supports the use of EPT
- ● negatively affects the use of EPT
- ☑ EPT is permissible
- ~ EPT is potentially allowable
- ☒ EPT is prohibited



★ Exception: EPT is permissible in Baltimore, Maryland.

Alabama
Alaska
Arizona

Summary Totals

Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
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Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming
Summary Totals

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AMERICAN BAR ASSOCIATION

ADOPTED BY THE HOUSE OF DELEGATES

AUGUST 11-12, 2008

RECOMMENDATION

RESOLVED, That the American Bar Association urges states, territories and tribes to support the removal of legal barriers to the appropriate use by health care providers of Expedited Partner Therapy (EPT), applied as specified in protocols promulgated by the U.S. Centers for Disease Control and Prevention, in the treatment of those sexually transmitted diseases identified in the evidence-based recommendations of the CDC and the policy statements of the American Medical Association (adopted June 2006).

REPORT

I. BACKGROUND AND INTRODUCTION

Despite major advances and achievements in the detection, treatment, and prevention of sexually transmitted diseases (STDs)[1] in the United States, infections such as chlamydia and gonorrhea remain significant public health challenges. The U.S. Centers for Disease Control and Prevention (CDC) estimates that over 700,000 new cases of gonorrhea[2] and 2.8 million new cases of chlamydia[3] occur each year. Traditional practices to inform, evaluate and treat sex partners of persons infected with STDs have relied upon patients or health care providers to notify partners of infected persons of their exposure to an STD.

Initially developed to help control syphilis, partner management became widely recommended for gonorrhea, chlamydial infection and, most recently, human immunodeficiency virus (HIV) infection. However, for STDs other than syphilis, partner management based on provider referral is rarely assured, while patient referral has had only modest success in assuring partner treatment. An alternative approach to assuring treatment of partners is expedited partner therapy (EPT). EPT is the delivery of medications or prescriptions by persons infected with an STD to their sex partners without clinical assessment of the partners.[4] Clinicians (e.g. physicians, nurse practitioners, physician assistants, pharmacists, public health workers) provide patients with sufficient medications directly or via prescription for the patients and their partners. This practice is intended to reduce the incidence of persistent or recurrent infection associated with cases where the STD-infected patient is engaging in ongoing sexual activity with partners whose concurrent infection is preventing adequate treatment,[5] and is traditionally used in conjunction with physician guidance to patients to notify their sex partners of the infection.[6]

The CDC produced an evidence review and associated guidance in 2006 on the use of EPT as an option for partner management for selected STDs and patients, based on 1) an internal review of scientific biomedical and behavioral evidence and 2) consultations including internal and external expertise from researchers, STD program managers, health departments, professional medical and public health organizations, and federal colleagues. CDC's guidance indicates that EPT is a "useful option to facilitate partner management among heterosexual men and women with chlamydial infection or gonorrhea."[7] Additionally, the American Medical Association (AMA) adopted policy in June, 2006 that supported the CDC's guidance on EPT as stated in the

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[1] The national Centers for Disease Control and Prevention (CDC) uses the terminology sexually transmitted diseases (STD) . To be consistent with CDC language, the acronym STD will be used in this document.
[2] Centers for Disease Control and Prevention. Fact Sheet – Gonorrhea, *available at* http://www.cdc.gov/std/Gonorrhea/STDFact-gonorrhea.htm (last visited November 30, 2007).
[3] Centers for Disease Control and Prevention. Fact Sheet – Chlamydia, *available at* http://www.cdc.gov/std/Chlamydia/STDFact-Chlamydia.htm (last visited November 30, 2007).
[4] H. Hunter Handsfield, M.D., et al., *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases*, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 4 (2006) (hereinafter "CDC White Paper").
[5] *Id.* at 10.
[6] *Id.* at 9.
[7] *Id.* at 6.

CDC White Paper.[8] The evidence-based recommendation of the CDC is that EPT is a useful option for the treatment of gonorrhea and chlamydia, but not for other STDs such as syphilis and trichomoniasis (see Section IV below).

EPT is typically a single-dose therapy with a broad-spectrum antibiotic. Where EPT is practiced, it can be done by giving the patient a dose for the patient's partner, or giving the patient a prescription for enough pills for both the patient and partner. It is possible that the patient could also give the partner's name (or a false name) for the prescription to be written by the physician for the partner.

Structured implementation of EPT according to CDC recommendations requires meeting various administrative requirements (e.g., prescription requirements, insurance and other payment issues), but the legality of EPT is largely unknown, even to members of groups traditionally attributed with responsibility for the legality of the practice.[9] In order for EPT to reach its full potential as a treatment mechanism for chlamydial infection or gonorrhea in accordance with CDC guidelines, the legality of the practice must be clarified and any statutory impediments removed.[10] To that end, the CDC and the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities collaborated to assess the legal framework regarding EPT, the results of which are posted on the following link: http://www.cdc.gov/std/ept/legal/default.htm.

II. CURRENT APPLICATIONS OF PATIENT-DELIVERED PARTNER THERAPY

Partner notification is a cornerstone practice used in the treatment of patients diagnosed with STDs and includes guidance for the infected patient to refer their sex partners for diagnosis and treatment of STD infection,[11] yet fewer than 20 percent of persons diagnosed with gonorrhea or chlamydia are offered assistance in notifying their sex partners.[12] Healthcare practitioners face the reality that despite referrals encouraging patients to have their sex partners tested and treated, many partners fail to receive adequate treatment and reinfection is a common scenario.[13] For example, a 2000 study showed that physicians across the country dispensed additional medications for partners of persons infected with gonorrhea or chlamydial infection on a widespread but essentially unregulated basis. Approximately one-half of the physicians surveyed practiced EPT one or more times, and an estimated one-seventh had done so on a

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[8] AMA Council on Scientific Affairs (CSA) Report 9 (A-05), June 2006.

[9] Matthew R. Golden, M.D., MPH, et al., *The Legal Status of Patient-Delivered Partner Therapy for Sexually Transmitted Infections in the United States*, 32 SEXUALLY TRANSMITTED DISEASES, Feb. 2005, 112-114, at 112 (February 2005).

[10] CDC White Paper, *supra* note 4, at 6.

[11] Matthew Hogben, PhD., et al., *Patient-Delivered Partner Therapy for Sexually Transmitted Diseases as Practiced by U.S. Physicians*, 32 SEXUALLY TRANSMITTED DISEASES, Feb. 2005, 101-105, at 101.

[12] Golden, MR, Hogben M, Handsfield HH, et al. Partner notification for HIV and STD in the United States: Low coverage for gonorrhea, chlamydial infection and HIV. Sex Transm Dis 2003: 30:490-496.

[13] STD Quarterly, *Evidence Supports Use of Patient-Delivered Partner Therapy for Sexually Transmitted Diseases*, CONTRACEPTIVE TECHNOLOGY UPDATE, May 1, 2005 e-newsletter.

frequent basis. Additionally, one study found that more than 25 percent of medical providers in New York City have reported "frequent use" of EPT when diagnosing gonorrhea or chlamydia.[14]

Proponents of EPT believe the inadequacies of current partner notification and referral guidance, combined with the increased incidence of persistent STD occurrence in the United States, warrant increased utilization of EPT and incorporation into clinical and public health policies.[15] Emily J. Erbelding, M.D., M.P.H. and Jonathan M. Zenilman, M.D., of Johns Hopkins University, deem the findings "a major advance for the control and prevention of STDs"[16] and conclude that "the use of expedited approaches designed to circumvent traditional evaluation by a clinician increases the chance of the exposed partner's receiving proper therapy and, most important, reduces the original partner's risk of infection."[17] EPT programs should include an educational component for medical providers authorized to dispense medications; the practice of EPT is designed to limit liability issues, as medical providers either dispense or prescribe standard medications, i.e. no medications known to be associated with extreme side effects.

The practice of EPT can be a useful tool in reducing the high rates of new cases of both gonorrhea and chlamydia that occur each year.[18] EPT is an increasingly attractive option for clinicians faced with large numbers of chlamydial infections, decreasing staff to assist with partner notification, and the difficulties of getting male partners to providers for an infection that generally has no symptoms and which has no adverse health outcomes for males. Scientific evidence indicates that the recurrence of STD infection can be better reduced by giving the index patient medication to deliver to their partner(s) than by giving the index patient a standard referral service.[19] The University of Washington in Seattle reported that "the provision of chlamydia or gonorrhea treatment directly to patients' sexual partners, without requiring the partners to visit a physician, significantly improved infection control in patients."[20] Existing data also suggests that patients treated with EPT are more likely to notify their partners in accordance with physicians' guidance.[21]

Based on studies reporting the success of EPT and a study outlining risk factors associated with failure to notify potentially infected sexual partners, Public Health-Seattle and King County (PHSKC) in Washington began a partner notification program in 2004 to treat cases of gonorrhea and chlamydia.[22] The program's main features included the routine use of partner-delivered patient therapy by medical providers treating heterosexual individuals with gonorrhea or

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[14] Rogers, ME, Opdyke KM, Blank S, et al. *Patient-delivered partner treatment and other partner management strategies for sexually transmitted diseases used by New York City healthcare providers.* Sex. Transm Dis 2007; 34:88-92

[15] Golden, *supra* note 12, at 685.

[16] Emily J. Erbelding, M.D., M.P.H. and Jonathan M. Zenilman, M.D., *Toward Better Control of Sexually Transmitted Diseases*, 352 NEW ENGLAND JOURNAL OF MEDICINE, 2005, 720-721, at 721.

[17] See *supra* note 16 at 720.

[18] See *supra* notes 2 and 3.

[19] Pharmaceutical Journal Online News, *Better Results for STIs if Patients Offered Treatment for Partners*, 274 THE PHARMACEUTICAL JOURNAL, Feb. 19, 2005, at 199.

[20] Kate Johnson, *Patient-Delivered Treatment for Partners Reduces Chlamydia and Gonorrhea; Infectious Diseases;* 7 FAMILY PRACTICE NEWS, Apr. 1, 2002, at 22

[21] Hogben, *supra* note 11 at 103.

[22] Golden, et al., *Evaluation of a Population-Based Program of Expedited Partner Therapy for Gonorrhea and Chlamydial Infection*, Sex Transm Dis 2007: Vol. 34, No. 8, p. 598-603.

chlamydia, and a case report forms designed to "triage patients at high risk for partner notification failure to receive public health partner notification assistance." With respect to the effectiveness of the Washington program, researchers found:

> 2) The use of PDPT by providers in King County increased almost 3-fold concurrent with implementation of the program;
> 3) Patients who received PDPT from their provider were significantly less likely than other recently infected persons to report having untreated partners;
> 4) Providers successfully used the modified case report form to selectively refer patients with untreated partners to public health;
> 5) Patients referred to public health by providers usually accepted some form of partner management assistance; and
> 6) The estimated percentage of persons with gonorrhea or chlamydial infection for whom all partners were treated rose from 39% to 65% concurrent with the institution of the partner notification program.[23]

Thus, the findings of the randomized trial performed by PHSKC in Washington demonstrates the usefulness of EPT by medical providers as a tool to assist patients in partner notification and partner treatment, which has an inverse effect on gonorrhea and chlamydia morbidity rates.

Between 2000 and 2004, CDC sponsored four randomized controlled trials (RTC) designed to 1) compare EPT with standard partner management approaches and 2) assess behavioral predictors of treatment and reinfection. By late 2004, all trials had concluded data collection and analysis. The evidence across trials suggested EPT resulted in an approximate 20 percent reduction rate in recurrent or persistent infections among those originally diagnosed with chlamydial infection, and a 60 percent or better reduction rate among those originally diagnosed with gonorrhea. All trials reported favorable behavioral correlates, including increased notification and treatment of sex partners, and fewer instances of unprotected intercourse.

Following these findings, CDC convened two expert consultations in 2004 and 2005 to review scientific evidence related to EPT and address operational issues affecting its implementation. In February 2006, CDC issued a report providing the background of EPT, evidence in support of the practice, and guidance for using EPT as an option for managing partners of heterosexual sex partners with gonorrhea or chlamydial infection."[24] In that report, CDC recommended EPT as a clinical option for heterosexual patients with gonorrhea or chlamydial infection. A trial based on EPT for women with trichomoniasis yielded null results and dubious behavioral correlates; CDC did not recommend routine use of EPT for patients diagnosed with trichomoniasis. CDC expects that partner management for syphilis be conducted with public health professional notification, where possible.

In 2008, the American Academy of Pediatrics passed the following resolution on EPT:

> Resolved, that the Academy develop a policy statement that supports the practice of expedited partner therapy (EPT), i.e., treating the sex partners of sexually transmitted

[23] See *supra* note 22 at 602.
[24] CDC Fact Sheet – Gonorrhea., *supra* note 2.

> infections (STI)-infected persons without requiring the partners' prior clinical evaluation as an alternative to traditional partner notification, and be it further
> Resolved, that the Academy support policies and support legislation that would allow a health care provider diagnosing *Chlamydia trachomatis* in an individual to prescribe or dispense antibiotics to that person's sex partner(s) without examining them.

In June 2006, The American Medical Association (AMA) House of Delegates passed the following resolution in support of CDC's guidance on the use of EPT:

> The following statements, recommended by the Council on Science and Public Health, were adopted as by the AMA House of Delegates as AMA policy and directive at the 2006 AMA Annual Meeting:
> 1. The AMA supports the Centers for Disease Control and Prevention's (CDC's) guidance on expedited partner therapy (EPT) that was published in its 2006 white paper, Expedited Partner Therapy in the Management of Sexually Transmitted Diseases. **(Policy)**
> 2. The AMA will continue to work with the CDC as it implements EPT, such as through the development of tools for local health departments and health care professionals to facilitate the appropriate use of this therapy **(Directive)**

In September 2006, CDC's *STD Treatment Guidelines* endorsed EPT for the first time:

> When medical evaluation, counseling, and treatment of partners cannot be done because of the particular circumstances of a patient or partner or because of resource limitations, other partner management options can be considered. One option is patient-delivered therapy, a form of expedited partner therapy (EPT) in which partners of infected patients are treated without previous medical evaluation or prevention counseling... Medications and prescriptions for patient-delivered therapy should be accompanied by treatment instructions, appropriate warnings about taking medications if pregnant, general health counseling, and advice that partners should seek personal medical evaluations, particularly women with symptoms of STDs or [pelvic inflammatory disease].[25]

EPT holds great potential as a tool in reducing the rate of persistent or recurrent STDs, and is touted as a major advance in the treatment of STDs. While EPT is not yet a widespread practice used by physicians in the treatment of STDs, it is used by some practitioners in both the private and public sectors. EPT is part of a host of guidance and advocacy tools, but it is still widely underused despite proven benefits in practice.

III. BARRIERS TO GREATER IMPLEMENTATION OF EPT

There are a number of barriers to the widespread use of EPT in the treatment of STDs, some of which are medical in nature. For example, some physicians are more likely to utilize EPT when treating heterosexual female index patients rather than heterosexual male index patients because

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[25] Centers for Disease Control and Prevention, *Sexually Transmitted Diseases Treatment Guidelines, 2006*, 55 MMWR 8 (2006), *available at* http://www.cdc.gov/std/treatment/2006/rr5511.pdf (last visited November 30, 2007).

of a general reluctance to treat the former for STDs without first performing a pregnancy test or screening for pelvic inflammatory disease.[26] In addition, EPT is contraindicated for STDs where the preferred treatment option is something other than an orally administered prescription, such as the treatment for syphilis.[27] Other barriers include physicians' concerns that the medication will not be delivered to their patients' sex partners, accidental dispensing of multiple dosage, and missed opportunities to counsel partners.[28]
However, one of EPT's greatest barriers is legal in nature. The results of one study indicated that despite its potential benefits, an overwhelming 75 percent of physicians did not use EPT because of concerns about liability.[29] According to a second study, 36 percent of primary care physicians do not use EPT out of fear of potential liability, even though approximately 90 percent agree that EPT helps them provide better care for their patients with chlamydia and protects their patients from reinfection.[30] Physicians are also joined by nurse practitioners in their uncertainty: 28 percent fear using EPT because it may expose them to the possibility of a lawsuit, although 50 percent of nurse practitioners agree that the practice protects their patients from reinfection.[31]

Physicians' and nurse practitioners' concerns are not without reason because the legal status of EPT is dishearteningly uncertain. For example, EPT is expressly forbidden in some states, while legal in others.[32] In addition, medical practice statutes may explicitly prohibit physicians from prescribing medication in the absence of a physician-patient relationship, and pharmacy boards may impose similar restrictions.[33] An additional study, primarily concerned with medical and pharmacy boards, demonstrated confusion regarding the legal status of EPT. In this study, three states' medical and pharmacy board respondents disagreed with one another when polled about the legality of EPT in their states.[34]

While further research may be performed to address many of the medical concerns facing EPT, the aforementioned legal concerns present a large measure of the barriers to greater use of EPT as a clinical tool in treating STDs that research alone cannot dispel. In order for EPT to achieve its potential as a treatment option, its legal barriers must be addressed.

IV. CDC GUIDANCE FOR THE APPROPRIATE IMPLEMENTATION OF EPT

As analyses of the data from the EPT RTCs were completed, CDC turned its attention to interpretation of the results and translating the research into clinical guidance. In 2005, CDC undertook a review of evidence and a broad-scope consideration of the practice's limitations and

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[26] Hogben, *supra* note 11 at 103.
[27] Erbelding and Zenilman, *supra* note 16 at 721.
[28] Linda M. Niccolai, Ph.D. and Diana M. Winston, M.P.H., *Physicians' Opinions on Partner Management for Nonviral Sexually Transmitted Infections*, 28 AMERICAN JOURNAL OF PREVENTIVE MEDICINE, 2005, 229-233, at 229.
[29] See *supra* note 28 at 230.
[30] Laura L. Packel, M.P.H., *Patient-Delivered Partner Therapy for Chlamydia Infections: Attitudes and Practices of California Physicians and Nurse Practitioners,* 33 SEXUALLY TRANSMITTED DISEASES, July 2006, 458-463, at 461 (*see* Tables 3 and 4).
[31] *Id.* at 461 (*see* Table 5).
[32] Erbelding and Zenilman, *supra* note 19 at 721.
[33] *Id.*
[34] Golden, *supra* note 9 at 113.

benefits.[35] The result of the review and consultation was a published white paper entitled "Expedited Partner Therapy in the Management of Sexually Transmitted Diseases: Review and Guidance." The CDC white paper represented a thorough, systematic review of available (published and unpublished) literature reviewing EPT and patient-delivered partner therapy.[36] The paper provided a detailed summary of concerns regarding the implementation of EPT on a larger scale, as well as precise guidance for the use of EPT in practice.

The medical issues highlighted in the CDC white paper covered the gamut of concerns that physicians and nurse practitioners express, as noted above.[37] In addition, the white paper addressed a range of implementation barriers to EPT: concerns about the coverage of direct and indirect costs related to EPT and the limitations on third-party coverage; administrative and practical considerations; missed opportunities for counseling; the attitudes and beliefs of health care providers and agencies, and confidentiality concerns.[38]

Significantly, the CDC has found that confidentiality concerns arising from a patient being called upon to communicate personal medical issues with sexual partners are not germane to EPT, but are relevant to all patient referral forms of partner management, which actually comprise the vast majority of partner treatment interactions in the U.S.[39] In addition, the white paper highlighted the current legal uncertainty of EPT, as well as isolated statutory impediments that exist in certain states.[40] Finally, the paper acknowledged a new barrier: that "[t]he medicolegal ramifications may be uncertain in the event of adverse outcomes in the recipients of EPT."

The white paper summarized these barriers into a listing of "implementation issues" affecting the utilization of EPT and its priority with respect to other, more traditional partner management strategies. The implementation issues are:

- limited study focus on special populations,
- possible presence of other STDs,
- STD co-morbidity in sex partners,
- potential effects of drug use,
- adverse effects of drug use,
- missed opportunities for prevention counseling,
- the uncertain legal status of EPT,
- medicolegal concerns of the risk (or perceived risk) of increased litigation,
- funding,
- privacy,
- drug delivery and packaging,
- the providers' and health agencies' attitudes and beliefs,
- administrative barriers,

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[35] Open Letter from John M. Douglas, Jr., M.D., Director, Division of STD Prevention, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention, Department of Health and Human Services (May 11, 2005) (*available at* http://www.cdc.gov/std/Dear ColleagueEPT5-10-05.pdf).
[36] CDC White Paper, *supra* note 4 at 4.
[37] CDC White Paper, *supra* note 4 at 6.
[38] *Id.* at 6.
[39] CDC/NCHHSTP, *Comments on AMA Report of the Council on Ethical and Judicial Affairs,* November 8, 2007.
[40] See *supra* note 4 at 6.

- provider education,
- interaction with other partner management strategies, and
- implications on retesting for chlamydial infection and gonorrhea.[41]

The white paper concludes that EPT is at least equivalent, if not better, than standard patient referral in preventing persistent or recurrent chlamydial or gonorrheal infection.[42] With all of the aforementioned implementation issues considered, the CDC white paper provides clear guidance for the use of EPT in practice. The CDC's recommendations are five-fold:

- **Gonorrhea and Chlamydial Infection in Women**: EPT can be used to treat the sex partners of female patients infected with gonorrhea or chlamydia when other management strategies are impractical or unsuccessful.
- **Gonorrhea and Chlamydial Infection in Men**: EPT can be used to treat the sex partners of male patients infected with gonorrhea or chlamydia when other management strategies are impractical or unsuccessful, provided that female recipients of EPT are strongly encouraged to seek medical attention (this is particularly important for female recipients exhibiting symptoms of acute pelvic inflammatory disease such as abdominal or pelvic pain) in addition to accepting therapy.
- **Gonorrhea and Chlamydial Infection in Men Having Sex with Men**: Because of a lack of statistically significant data regarding the efficacy of EPT in this population (because of high risk of co-morbid, undiagnosed HIV), EPT is not suggested as a routine therapy for the male sex partners of male patients infected with gonorrhea or chlamydial infection. EPT is only suggested for selective use, with caution, when other strategies prove impractical or unsuccessful.
- **Women with Trichomoniasis**: Because of a high-risk of STD co-morbidity in sex partners (especially gonorrhea and chlamydial infection), EPT is not advised for use as a routine therapy for female patients with trichomoniasis. EPT is only suggested for use selectively, with caution, when other strategies prove impractical or unsuccessful.
- **Syphilis**: EPT is not suggested for use in the treatment of patients with infectious syphilis. Syphilis typically requires injection therapy, and partner notification services are ordinarily available at local or state health departments.[43]

In summary, the CDC concludes that EPT is a useful option in the facilitation of partner management, particularly for the treatment of male partners of women with gonorrhea or chlamydia and the treatment of female partners of men with gonorrhea or chlamydia, and recommends the use of EPT as a tool in the prevention of persistent or recurrent gonorrhea or chlamydial infection in the treatment of women diagnosed with gonorrhea or chlamydia, or in the treatment of heterosexual men diagnosed with gonorrhea or chlamydial infection.[44] EPT is not recommended for use in treating chlamydia or gonorrhea in men who have sex with men because of high rates of undiagnosed HIV and other STDs. EPT is also not recommended for treatment of chlamydia or gonorrhea among homosexual women because no data currently exist

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[41] *Id.* at 18-24.
[42] *Id.* at 34.
[43] CDC White Paper, *supra* note 4 at 6.
[44] American Medical Association, *Report 7 of the Council on Science and Public Health (A-06)* (Jun. 21, 2006) (*available at* http://www.ama-assn.org/ama/pub/category/print/16410.html).

demonstrating the efficacy or role of EPT among this population.[45] Finally, existing data support the practice of EPT in treating chlamydia and gonorrhea only, because other STDs frequently require more invasive treatment procedures or medications with higher rates of allergic reactions. For example, EPT would be inappropriate for use in treating syphilis because the disease frequently requires injection therapy and many patients have allergic reactions to penicillin.

These guidelines are supported by the American Medical Association, whose House of Delegates passed a supporting resolution in June, 2006. The AMA's recommendation adopts the CDC guidelines and pledges to support the CDC in the implementation of appropriate use of EPT.[46] The American Academy of Pediatrics adopted a resolution in 2008 encouraging the practice of EPT and supporting policies and legislation allowing physicians to dispense medication for chlamydia to a person's sexual partners without first examining them. The next step in addressing the implementation issues outlined in the CDC white paper is to address legal barriers to the use of EPT.

V. STATE-LEVEL LEGAL ANALYSIS OF THE LEGAL STATUS OF EPT

CDC and the *Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities* (*Center*) collaborated to assess the state-level legal framework concerning EPT to assist state and local STD programs in their efforts to implement EPT as an additional partner management tool.[47] The primary research objective was to identify legal provisions that impact a clinician's ability to provide a prescription for a patient's sex partner, without prior evaluation of that partner, for purposes of treating an STD (specifically chlamydia or gonorrhea). Three broad legal frameworks were examined: 1) medical licensing and liability, 2) public health and safety, and 3) pharmaceutical practices. The examination of pharmaceutical practices focused on laws concerning drugs generally, and "legend" drugs (which require a prescription, such as most antibiotics), but not laws concerning controlled substances (e.g., habitual drugs regulated under the federal Controlled Substances Act[48]). Antibiotics used to treat chlamydia and gonorrhea are not controlled substances.

In each of these three major areas, research included interpretive analysis of relevant laws and policies (i.e. statutes, bills, administrative regulations, judicial cases, administrative opinions) found through legal research engines (e.g., Westlaw, LEXIS), and publicly-available legal Websites. Secondary resources (e.g., reports, articles, media accounts) and informal discussions with federal, state, and local law and policy-makers, public health officials, and academics were used sparingly to gather some data. Information from these sources was confirmed through original legal research. Data were organized in a table that stratified references to relevant statutes, administrative regulations, cases, legislative bills, administrative orders, and medical or pharmaceutical board opinions. Tables are available in hard copy and on the CDC website at:

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[45] CDC White Paper, *supra* note 4 at 33.

[46] See *supra* note 4 at 33.

[47] James G. Hodge, Jr., J.D., L.L.M. and Erin Fuse Brown, J.D., M.P.H., Assessing Legal and Policy Issues Concerning Expedited Partner Therapies for Sexually Transmitted Diseases 2 (Jul. 27, 2006) (unpublished report, on file with James G. Hodge at The Center for Law and the Public's Health at Johns Hopkins Bloomberg School of Public Health).

[48] Controlled Substances Act, 21 U.S.C. § 801et seq.

http://www.cdc.gov/std/ept/legal/default.htm. Included in the tables are hotlinks to relevant legal documents analyzed and used to draw conclusions about the legal status of EPT in each state.

For each jurisdiction, one of three possible conclusions is offered, based on this assessment of the multifarious laws and policies: 1) *EPT is permissible* (because the laws within the jurisdiction either expressly allow the practice of EPT, or do not expressly prohibit it); 2) *EPT is possible* (because the laws within the jurisdiction may allow EPT subject to specific interpretations of inconsistent or amorphous provisions, supporting policies underlying legal authorization, or incorporation by reference of current STD treatment guidelines); or 3) *EPT is likely prohibited* (because the laws within the jurisdiction do not support the practice of EPT by clinicians or others).[49] The findings indicate that EPT is permissible or possible in a majority of jurisdictions. At present, EPT is *permissible* in 10 jurisdictions, *possible* in 29 jurisdictions, and *likely prohibited* in 13 jurisdictions.[50]

One question that arises is whether EPT might present confidentiality or privacy concerns for the partner, especially since the underlying premise of EPT is that the partner may not know of the infection or has chosen not to visit the doctor to be treated. EPT need not be invasive of the privacy of the partner. For example, it is possible to practice EPT by providing the antibiotic drug directly to the patient for use by the partner, or a prescription to the patient for a dose that is adequate for both patient and partner. The antibiotic is broad-spectrum antibiotic and thus in itself should not label the patient or partner as having or potentially having an STD, even if the prescription were written to the partner's name. Since STDs are required to be reported by physicians to the state health department under state laws, EPT should not be any more invasive of privacy than current public health practice.

As noted above, the threat of medical malpractice liability might pose a barrier to EPT. These legal issues would need to be addressed by states, such as through adoption of protocols on how to appropriately implement EPT.

VI. CASE STUDY: LEGAL IMPLEMENTATION OF EPT IN MARYLAND

Senate Bill 349 was signed into law on April 24, 2007, establishing a three-year Expedited Partner Therapy Pilot Program (Program) in the Baltimore City Health Department. The purpose of the Program is "to provide antibiotic therapy to a partner of a patient diagnosed with a sexually transmitted infection of gonorrhea or chlamydia in order to contain the infection and prevent further transmission."[51] Under the Program, medical providers, including licensed physicians, certified nurse practitioners, and physician assistants, may dispense antibiotic therapy for the partners of patients presenting with gonorrhea or chlamydia without a prior physical examination.[52] The Fiscal and Policy Note accompanying the Bill specifically cited CDC's inclusion of EPT in the 2006 Sexually Transmitted Diseases Treatment Guidelines as providing validity for the practice of EPT.[53] In addition, the Fiscal and Policy Note discussed the "Legal

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[49] Hodge, *supra* note 47 at 5.
[50] See *supra* note 47 at 5.
[51] MD. CODE REGS. 10.06.01.17-1 (2007)
[52] *Id.*
[53] http://mlis.state.md.us/2007RS/fnotes/bil_0009/sb0349.pdf

Assessment Concerning Expedited Partner Therapies" produced jointly by NCHHSTP/CDC and the Center for Law and the Public's Health as legal support for EPT's practice.[54] The Program, which took effect on July 1, 2007, will remain effective for 3 years.[55] At the end of each calendar year, the Baltimore City Health Department must submit a report to the Governor and the General Assembly detailing the "operation and performance" of the Program.[56] [57]

VII. ABA COLLABORATION WITH CDC

The ABA works diligently in addressing innovative issues in health law. In addition, the ABA has an ongoing collaboration with the CDC as documented in a Memorandum of Understanding signed by the two organizations.[58] The Memorandum of Understanding joins the ABA and CDC in a mission to address issues relating to public health and the law. This resolution is a step that furthers that mission.

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[54] *Id.*

[55] MD. CODE REGS. 10.06.01.17-1 (2007)

[56] MD. CODE ANN., [Health-General] § 18-214.1(f) (West 2007)

[57] The report for this program is not publically available.

[58] Memorandum of Understanding between the Centers for Disease Control and Prevention and the American Bar Association, signed March 7, 2005, *available at* http://www2a.cdc.gov/phlp/docs/ABA.CDC.MOU.pdf (last visited January 11, 2007).

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VIII. CONCLUSIONS

EPT is a useful tool in the fight against the increasing incidence of persistent and recurrent gonorrhea and chlamydial infection in the United States. Evidence substantiates the safety and usefulness of EPT in practice, and the CDC white paper addresses continuing issues to implementation. These issues encompass a number of medical and legal concerns faced by physicians, nurse practitioners, and pharmacists in the implementation of EPT. The CDC's white paper proposes a clear set of guidelines for the use of EPT in practice today. This guidance allows for the use of EPT in the treatment of female sex partners of men and the male sex partners of women infected with gonorrhea or chlamydia. The AMA's adoption of the CDC's guidance and its and the American Academy of Pediatrics' support in the implementation of EPT will address many of the medical issues hindering EPT's widespread use by physicians and nurse practitioners, but cannot address the legal barriers.

Those in the legal profession have an opportunity to address the legal issues hindering EPT's potential to reduce the rates of recurrent and persistent infections of gonorrhea and chlamydia. The ABA's unique collaborative relationship with CDC makes the joint Memorandum of Understanding the prime vehicle for exploring the legal barriers to implementation of EPT on a larger scale, the success for which is dependent upon ABA support.

Therefore, the recommendations set forth above are consistent with the ABA's missions and goals, in particular Goals III and IV, respectively, "To provide ongoing leadership in improving the law to serve the changing needs of society" and "To increase public understanding of and respect for the law, the legal process, and the role of the legal profession."[59]

Respectfully submitted,

Andrew J. Demetiou
Chair
Health Law Section
American Bar Association

August 2008

[59] American Bar Association, *ABA Mission and Association* Goals, *available at* http://www.abanet.org/about/goals.htm (last visited July 24, 2006).

GENERAL INFORMATION FORM

To Be Appended to Reports with Recommendations
(Please refer to instructions for completing this form.)

Submitting Entity: Health Law Section

Submitted By: Andrew J. Demetriou, Chair

1. Summary of Recommendation(s).

   The report and recommendation urges the American Bar Association to support the elimination of legal barriers to the provision by healthcare providers of Expedited Partner Therapy (EPT) in the treatment of certain sexually transmitted diseases identified by the U.S. Centers for Disease Control and Prevention and the policy statements of the American Medical Association on this issue, and to address any potential medico-legal implications posed by the practice of EPT.

2. Approval by Submitting Entity.

   Approved by Section Council May 6, 2008.

3. Has this or a similar recommendation been submitted to the House or Board previously?

   No.

4. What existing Association policies are relevant to this recommendation and how would they be affected by its adoption?

   There are no Association policies addressed by this recommendation.

5. What urgency exists which requires action at this meeting of the House?

   The need to address the over 700,000 new cases of gonorrhea and 2.8 million cases of chlamydia that occur each year makes action needed as soon as possible.

6. Status of Legislation. (If applicable.)

   None pending.

7. Cost to the Association. (Both direct and indirect costs.)

   None.

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8. Disclosure of Interest. (If applicable.)

None.

9. Referrals.

This report and recommendation has been referred to the Sections of Individual Rights and Responsibility, Science & Technology, Litigation, Torts, Trial and Insurance Practice, and Administrative Law, and the Young Lawyers and General Practice, Solo and Small Firm Divisions, and the Standing Committee on Medical Professional Liability.

10. Contact Person. (Prior to the meeting.)

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11. Contact Person. (Who will present the report to the House.)

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Executive Summary

Summary of Recommendation

The report and recommendation urges the American Bar Association to support the elimination of legal barriers to the provision by healthcare providers of Expedited Partner Therapy (EPT) in the treatment of certain sexually transmitted diseases identified by the U.S. Centers for Disease Control and Prevention and the policy statements of the American Medical Association on this issue, and to address any potential medico-legal implications posed by the practice of EPT.

Summary of issues which the recommendation addresses

The recommendation calls for States, Territorial and Tribal governments to eliminate laws that would prohibit doctors from utilizing this treatment option, consistent with recommendations of the US CDC.

Explanation of how the proposed policy position will address the issue

The policy will encourage states, tribes and territories to eliminate statutory barriers to implementing the Expedited Partner Therapy (EPT)

Summary of minority views or opposition which have been identified

No opposing views have been identified.